K091821

Section 5 – 510(k) Summary

AUG 2 6 2009

Submitter:	Cardiocom, LLC 7980 Century Boulevard, Chanhassen, MN 55317
Contact Person:	Daniel Cosentino, CEO, President, Cardiocom, LLC 612-669-5890(C) 888-320-8881(F)
Date Prepared:	June 17, 2009
Trade Name:	Commander III
Classification:	Class II Noninvasive Blood Pressure Measurement System - 21 CFR §870.1130 Oximeter – 21 CFR §870.2700
Product Code:	DXN, DQA
Predicate Device(s):	The subject device is equivalent to the following device: Cardiocom Commander III, K053303
Device Description:	The Commander III is an FDA cleared device (K053303, K053304). It is similar to a simple personal computer with a modem that stores and transmits data to remote locations. The Commander III is cleared for use with a pulse oximeter, a weight scale, a glucose meter, a peak flow meter and a blood pressure cuff. This premarket submission seeks to add an additional pulse oximeter, the PO100, for use with the Commander III. The PO100 is a reusable pulse oximeter that connects to the Cardiocom Commander III via a cable in the same manner as the currently cleared pulse oximeter.
Intended Use:	The Commander III is for use by patients to collect and transmit general health questions and patient vital sign data (such as weight, blood pressure, glucose, pulse oximetry, peak flow) between the patient, typically at home, and a health care professional at a remote site.
Functional and Safety Testing:	To verify that device design met its functional and performance requirements, representative samples of the device underwent electrical, mechanical and clinical testing in accordance with applicable industry standards.
Conclusion:	Cardiocom considers the Commander III to be equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

AUG 2 5 2009

Cardiocom, LLC
c/o Mr. Daniel Cosentino
CEO, President
7980 Century Blvd.
Chanhassen, MN 55317

Re: K091821
Trade/Device Name: Commander 111, Model CD300-CD399
Regulation Number: 21 CFR 870.1130
Regulation Name: System, Measurement, Blood Pressure, Non-invasive
Regulatory Class: Class II (two)
Product Code: DXN, DQA
Dated: July 27, 2009
Received: July 29, 2009

Dear Mr. Cosentino:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 – Indications for Use Statement

Device Name: Commander III

The Commander III is for use by patients to collect and transmit general health questions and patient vital sign data (such as weight, blood pressure, glucose, pulse oximetry, peak flow) between the patient, typically at home, and a health care professional at a remote site.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K091821